

§ 26.157

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in effect are maintained. (Specific contents of the procedures are described in § 26.157.)

(5) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; maintaining acceptable analytical performance for all controls and standards; maintaining quality control testing; and assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(6) This individual shall be responsible for taking all remedial actions that may be necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, including errors in result reporting or in the analysis of performance testing results. This individual shall ensure that test results are not reported until all corrective actions have been taken and he or she can assure that the test results provided are accurate and reliable.

(b) *Certifying scientist.* (1) HHS-certified laboratories shall have one or more certifying scientists who review all pertinent data and quality control results to certify the laboratory's test results.

(2) A certifying scientist shall be an individual with at least a bachelor's degree in the chemical or biological sciences, medical technology, or an equivalent field who reviews all pertinent data and quality control results. The individual shall have training and experience in the theory and practice of all methods and procedures used in the laboratory, including a thorough understanding of chain-of-custody procedures, quality control practices, and analytical procedures relevant to the results that the individual certifies. Relevant training and experience must also include the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial action to be taken in response to aberrant test or quality control results, or a determination that test systems are out of control limits.

(3) A laboratory may designate certifying scientists who only certify results that are reported negative and

certifying scientists who certify results that are reported both negative and adulterated, substituted, dilute, or invalid.

(c) *Day-to-day operations and supervision of analysts.* HHS-certified laboratories shall assign one or more individuals who are responsible for day-to-day operations and supervision of the technical analysts. The designated individual(s) shall have at least a bachelor's degree in the chemical or biological sciences, medical technology, or an equivalent field. The individual(s) shall also have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; review, interpretation, and reporting of test results; maintenance of the chain of custody; and proper remedial actions to be taken in response to aberrant test or quality control results, or the finding that test systems are out of control limits.

(d) *Other personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for their assigned tasks.

(e) *Training.* HHS-certified laboratories shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* At a minimum, each laboratory personnel file must include a résumé, any professional certification(s) or license(s), a job description, and documentation to show that the individual has been properly trained to perform his or her job.

§ 26.157 Procedures.

(a) HHS-certified laboratories shall develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens.

(b) Written chain-of-custody procedures must describe the methods to be used to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to another HHS-certified laboratory, if required, and continuing until final disposition of specimens.

(c) HHS-certified laboratories shall develop, implement, and maintain a written manual of standard operating procedures for each assay performed for licensees and other entities for drug and specimen validity testing. The procedures must include, but are not limited to, detailed descriptions of—

- (1) The principles of each test;
- (2) Preparation of reagents, standards, and controls;
- (3) Calibration procedures;
- (4) Derivation of results;
- (5) Linearity of methods;
- (6) Sensitivity of the methods;
- (7) Cutoff values;
- (8) Mechanisms for reporting results;
- (9) Controls;
- (10) Criteria for unacceptable specimens and results;
- (11) Reagents and expiration dates; and
- (12) References.

(d) HHS-certified laboratories shall develop, implement, and maintain written procedures for instrument setup and normal operation, including the following:

- (1) A schedule for checking critical operating characteristics for all instruments;
- (2) Tolerance limits for acceptable function checks; and
- (3) Instructions for major troubleshooting and repair.

(e) HHS-certified laboratories shall develop, implement, and maintain written procedures for remedial actions to be taken when errors are detected or systems are out of acceptable limits.

The laboratory shall maintain documentation that its personnel follow these procedures and take all necessary corrective actions. In addition, the laboratory shall have systems in place to verify all stages of testing and reporting and to document the verification.

§ 26.159 Assuring specimen security, chain of custody, and preservation.

(a) The HHS-certified laboratories performing services for licensees and other entities under this part shall be secure at all times. Each laboratory shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes

or areas where records are stored. Access to these secured areas must be limited to specially authorized individuals whose authorization is documented. All authorized visitors, and maintenance and service personnel, shall be escorted at all times in the laboratory, except personnel who are authorized to conduct inspections and audits on behalf of licensees, other entities, the NRC, or the HHS Secretary, and emergency personnel (including but not limited to firefighters and medical rescue teams).

(b) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and shall compare information on specimen bottles within each package to the information on the accompanying custody-and-control forms.

(1) Any direct evidence of tampering or discrepancies in the information on the specimen bottles and the custody-and-control forms attached to the shipment must be reported to the licensee or other entity within 24 hours of the discovery and must be noted on the custody-and-control forms for each specimen contained in the package. When notified, the licensee or other entity shall ensure that an investigation is initiated to determine whether tampering has occurred.

(i) If the investigation determines that tampering has occurred, the licensee or other entity shall ensure that corrective actions are taken.

(ii) If the licensee or other entity has reason to question the integrity and identity of the specimens, the specimens may not be tested and the licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, if the licensee testing facility has retained the specimen in Bottle B, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.